

Strategic Partnership III Track A

RFA 13-03A: CIRM Strategic Partnership III Awards - Track A

The purpose of the Strategic Partnership Awards Initiative ("Initiative") is to attract industry engagement and investment in CIRM funded stem cell research. The intent of the Initiative is to create incentives and processes that will: (i) enhance the likelihood that CIRM funded projects will obtain funding for future clinical trials (e.g. follow-on financing), (ii) provide a source of co-funding for the earlier stages of clinical development, and (iii) enable CIRM funded projects to access expertise within pharmaceutical and large biotechnology partners in areas such as discovery, preclinical, regulatory, clinical trial design and manufacturing process development.

This Initiative requires applicants to show evidence of either having the financial capacity to move the project through development or of being able to attract the capital to do so. This may be evidenced by, for example, (i) significant investment by venture capital firms, large biotechnology or pharmaceutical companies, disease foundations and/or through the public markets; and financial statements evidencing significant liquid assets; or (ii) a collaborative research agreement with a large biotechnology or pharmaceutical company. The agreement with the large biotechnology or pharmaceutical company need only cover co-funding and collaboration support for the proposed project (and not future development).

CIRM intends to offer repeat calls under this initiative every 6-9 months. The focus, scope and objective may differ with each solicitation.

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A Track A award will provide funding for a single development project for a single therapeutic candidate per applicant over a project period of up to 4 years. Under Track A, a non-profit Principal Investigator (PI) may submit a single application, and a for-profit organization may submit a single application.

Please see the RFA for full details.

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CIRM conducted a webinar for prospective applicants on August 7, 2013 to address questions about the RFA and application process. To view the recording or access a summary of the Q and A, go to <https://www.cirm.ca.gov/our-funding/webinar-cirm-strategic-partnership-iii-awards>.

Application Process

Submission of an application for a CIRM Strategic Partnership III Award involves a two-step process. An eligible applicant must first submit a Letter of Intent (LOI) to CIRM following the instructions below. In the second step of the process, eligible applicants will submit a full application. **The Principal Investigator and the project proposed in the application must be the same as those described in the LOI; otherwise, the application is deemed ineligible.**

LOI Submission Instructions:

The Letter of Intent (LOI) must be submitted via the CIRM Grants Management Portal, as follows:

1. Go to the Grants Management Portal (https://grants.cirm.ca.gov/login/upgrade_browser) and log in with your existing CIRM Username and Password. If you do not have a Username, click on the "New User" link and follow the instructions to create a CIRM Username and password.
2. After logging in, your home page will display a list of open RFAs or LOIs. Click on the "Start a Letter of Intent" link located to the right of the section labeled "RFA 13-03A: CIRM Strategic Partnership III Track A: Letter of Intent"
3. Complete the LOI by following the posted instructions.
4. The "Done with Letter of Intent" button becomes enabled when all sections are complete. Select this button to complete your LOI submission. Once this button has been selected, you will no longer be able to make changes to your LOI.
5. To ensure the process is complete, click on the "Menu" tab and select "Your Submitted Applications" from the drop down list. Your

submission for the relevant RFA ("RFA 13-03A: CIRM Strategic Partnership III Track A") should appear in the table labeled "Your Submitted Applications".

The LOI must be received by CIRM no later than **5:00 pm (PDT) on August 22, 2013** via the CIRM Grants Management Portal. No exceptions to this deadline will be made.

Application Instructions and Forms

Application forms will be available on the CIRM website https://grants.cirm.ca.gov/login/upgrade_browser in late August 2013. Only those applicants that submitted an LOI that was accepted by CIRM may submit an application. **Applicants will be notified if their LOI was NOT accepted.**

The application for RFA 13-03A Track A consists of up to ten parts:

- Part A: Application Information Form (Web-based form)
- Part B: Strategic Partnership III Award Proposal (MS Word template)
- Part C: Biographical Sketches for Key Personnel (MS Word template)
- Part D: Due Diligence Report
- Part E: Activity Based Budget
- Part F: FDA correspondence
- Part G: Clinical Protocol
- Part H: Investigator Brochure
- Part I: Copies of authorization for cross reference of Drug, Device or Facility master files
- Part J: Licenses and agreements (MTAs)

All applicable parts of the Application for RFA 13-03A: CIRM Strategic Partnership III Track A must be submitted together and received by CIRM no later than **5:00 PM PDT on October 21, 2013** via the CIRM Grants Management Portal. It is the applicant's responsibility to meet this deadline; no exceptions will be made.

Schedule of CIRM Deadlines and Reviews	Date
LOI due	5:00 pm (PDT), August 22, 2013
Applications due	5:00 pm (PDT), October 21, 2013
Supplemental Information Due	5:00 pm (PST), January 6, 2014
Scientific Review of Applications by Grants Working Group (GWG)	February, 2014
Review and Approval by ICOC/Application Review Subcommittee	Q2, 2014

Contacts

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ICOC approval:

May 29, 2014

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